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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Praziquantel Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for use of oral praziquantel tablets for the removal of certain tapeworm parasites in dogs.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lonnie.luther@fda.gov.*

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200–265 that provides for use of PRAZI–C (praziquantel) Tablets for the removal of certain tapeworm parasites in dogs. Phoenix Scientific, Inc.'s PRAZI–C Tablets are approved as a generic copy of Bayer HealthCare LLC's Tape Worm Tabs approved under NADA 111–798. The supplemental ANADA is approved as of September 15, 2004, and the regulations are amended in 21 CFR 520.1870 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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200-265

NFR 1

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.1870 is amended by revising paragraph (b)(2) to read as follows:

§ 520.1870 Praziquantel tablets.

* * * * *

(b) * * *

(2) No. 059130 for use of the product described in paragraph (a)(1) of this section, as in paragraph (c)(1) of this section.

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Dated: October 14, 2004
October 14, 2004.

Steven D. Vaughn
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine
[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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